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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,958	09/28/2005	Jens Pohl	2923-725	1440
6449	7590	04/10/2008		
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			EXAMINER KEMMERER, ELIZABETH	
			ART UNIT 1646	PAPER NUMBER
			NOTIFICATION DATE 04/10/2008	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/550,958	POHL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Elizabeth C. Kemmerer, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 22 January 2008.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-28 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ .  | 6) <input type="checkbox"/> Other: _____ .                        |

## DETAILED ACTION

### ***Status of Application, Amendments, And/Or Claims***

The amendment of 22 January 2008 has been entered in full. Claims 1-28 are under examination.

### ***Withdrawn Objections And/Or Rejections***

The objection to claim 4 for informalities as set forth at p. 2 of the previous Office Action (mailed 26 September 2007) is *withdrawn* in view of the amended claim (22 January 2008).

The rejection of claims 24-27 under 35 U.S.C. §§ 101 and 112, second paragraph, as set forth at pp. 3-4 of the previous Office Action (mailed 26 September 2007) is *withdrawn* in view of the amended claims (22 January 2008).

The rejection of claims 1-5, 8, 11-16, 18, 22, and 24-27 under 35 U.S.C. § 102(b) as being anticipated by EP 0567391A1 as set forth at pp. 7-8 of the previous Office Action (mailed 26 September 2007) is *withdrawn* in view of the amended claims (22 January 2008).

The rejection of claims 6, 7, 9, and 10 under 35 U.S.C. § 103(a) as being unpatentable over EP 0567391A1 in view of EP 1074620A1 as set forth at pp. 8-9 of the previous Office Action (mailed 26 September 2007) is *withdrawn* in view of the amended claims (22 January 2008).

The rejection of claims 24-27 under 35 U.S.C. § 112, first paragraph, as set forth at pp. 4-6 of the previous Office Action (mailed 26 September 2007) is *withdrawn in part* in view of the amended claims (22 January 2008).

### ***35 U.S.C. § 112, First Paragraph - New Matter***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 and dependent claims 2-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 has been amended to recite use of a buffer or solvent which has an ionic concentration of 100 mmol/l or less and is capable of maintaining a pH above 9.5 during the coating procedure. Support for such language in the specification as originally filed was not particularly pointed out by Applicant in the response, and the examiner could not independently identify support for the new language.

### ***35 U.S.C. § 112, First Paragraph - Enablement***

Claims 24-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treating subjects in need of

osteoinduction, comprising administering the composition of claim 1 to said subject in an amount effective to achieve osteoinduction, does not reasonably provide enablement for the therapeutic methods as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The basis for this rejection is essentially as set forth in the previous Office Action. However, in view of the amended claims and upon further consideration, it is clear that the methods read on therapeutic methods of osteoinduction, which is enabled.

Applicant's arguments (pp. 8-10, remarks received 22 January 2008) have been fully considered but are not found to be persuasive for the following reasons.

Applicant argues that the issue regarding preventing has been overcome in view of the claim amendments. This point is conceded.

Applicant argues that terms may be used in a manner contrary or inconsistent with one or more of their meanings if the written description clearly redefines the terms. Applicant urges that "osteoinductive material" has been defined in the specification as a biological device comprising at least a matrix material and a morphogenetic protein temporarily immobilized within and/or on the surface of said matrix material. Applicant argues that the use of the term "osteoinductive material" is not meant to limit the use to the area of bone repair. This has been fully considered but is not found to be persuasive. The specification has not taught how to successfully practice the claimed methods of using osteoinductive material to achieve the required results in their full

scope. For example, claim 25 recites an almost exhaustive list of tissues in the mammalian body.

Applicant argues that the previous Office Action admits that the state of the art shows that many members of the TGF- $\beta$  superfamily of proteins have activity on diverse tissues. Applicant also points to guidance in the specification regarding how to make and administer such proteins. Applicant concludes that no undue experimentation would be required. This has been fully considered but is not found to be persuasive because the specification has not taught how to use the claimed compositions, comprising osteoinductive proteins *and a matrix*, to treat tissues unrelated to bone. For example, the specification at pp. 6-7 describe suitable matrix materials which have all been used in the prior art in combination with osteoinductive proteins to grow bone. However, no evidence has been brought forth that this combination of osteoinductive protein and matrix can be used to grow tissues unrelated to bone, such as nerves, for example, which are specifically required by the claims.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (571) 272-0874. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D. can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ECK

/Elizabeth C. Kemmerer/  
Primary Examiner, Art Unit 1646